United States Court of Appeals for the Federal Circuit

2006-1572

IN RE GABAPENTIN PATENT LITIGATION

WARNER-LAMBERT CO., PFIZER, INC.,
and GODECKE AKTIENGESELLSCHAFT,
Plaintiffs-Appellants,

v.

PUREPAC PHARMACEUTICAL CO. and FAULDING, INC.,
Defendants-Appellees,

and

WATSON LABORATORIES, INC., WATSON PHARMACEUTICALS, INC.,
WATSON PHARMA, INC., and DANBURY PHARMACAL, INC.,
Defendants,

and

TEVA PHARMACEUTICAL INDUSTRIES, LTD. and TEVA PHARMACEUTICALS USA, INC.,
ZENITH LABORATORIES, INC. (now known as IVAX Pharmaceuticals NV, Inc.), ZENITH
GOLDLINE PHARMACEUTICALS, INC. (now known as IVAX Pharmaceuticals, Inc.)
and IVAX CORP.,
Defendants-Appellees,

and

APOTEX CORP., APOTEX, INC., and TORPHARM, INC.,
Defendants-Appellees,

and

EON LABS MANUFACTURING, INC.,
Defendant-Appellee.

Jack B. Blumenfeld, Morris, Nichols, Arsht & Tunnell LLP, of Wilmington, Delaware, argued for plaintiffs-appellants. With him on the brief were Karen Jacobs Louden, Benjamin Schladweiler, and Richard J. Bauer.

Edgar H. Haug, Frommer Lawrence & Haug LLP, of New York, New York, argued for defendants-appellees, Purepac Pharmaceutical Co. and Faulding, Inc. With him on the brief were Steven M. Amundson and Andrew S. Chalson.

Steven J. Lee, Kenyon & Kenyon LLP, of New York, New York, argued for defendants-appellees, Teva Pharmaceutical Industries, Ltd., et al. With him on the brief was Elizabeth Holland. Of counsel were William G. James, II and Patrice P. Jean of Washington, DC.

Richard J. Basile, St. Onge Steward Johnston & Reens LLC, of Stamford, Connecticut, for defendant-appellee, Eon Labs Manufacturing, Inc. With him on the brief were Stephen P. McMamara and Stanley H. Lieberstein. Of counsel were James P. Jeffry and Benjamin J. Lehberger.

Appealed from: United States District Court for the District of New Jersey

Judge John C. Lifland

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Defendant-Appellee.

DECIDED: September 21, 2007

Before LOURIE, LINN, and MOORE, Circuit Judges.

LOURIE, Circuit Judge.

Warner Lambert Co., Pfizer Inc., and Gödecke Aktiengesellschaft (collectively "Warner Lambert") appeal from the judgment of the United States District Court for the District of New Jersey granting summary judgment of noninfringement of claims 7-11 of U.S. Patent 6,054,482 ("the '482 patent") in favor of appellees Purepac Pharmaceutical Co., Faulding Inc., Teva Pharmaceutical Industries, Inc., Teva Pharmaceuticals USA, Inc. (collectively "Teva"), Zenith Laboratories, Inc. (now known as IVAX Pharmaceuticals NV, Inc.), Zenith Goldline Pharmaceuticals, Inc. (now known as IVAX Pharmaceuticals, Inc), IVAX Corp. (collectively "IVAX"), and Eon Labs Manufacturing, Inc. (generic defendants collectively referred to as "appellees"). Because we conclude that the district court erred in determining that there were no genuine issues of material fact concerning whether Warner Lambert failed to meet its burden of proof that the accused products infringe the asserted claims of the '482 patent, we reverse and remand. Because we conclude that the district court did not err in construing the disputed claim limitations, we affirm those aspects of the district court's decision.

BACKGROUND

Warner Lambert manufactures and sells Neurontin®, a drug used to treat certain cerebral disorders, including epilepsy. The active ingredient in Neurontin® is a compound called gabapentin, which is covered by Warner Lambert's '482 patent. That patent, entitled "Lactam-Free Amino Acids," is directed towards a process for the preparation of, and compositions containing, gabapentin substantially free from a lactam contaminant. '482 patent col.2 ll.27-29.

Warner Lambert scientists discovered that under certain conditions gabapentin has a tendency to form a lactam, which makes the drug unstable and unsafe. The lactam was shown to be twenty-five times more toxic than gabapentin, and is linked to causing seizures, rather than preventing them. In re Gabapentin Patent Litig., 393 F. Supp. 2d 278, 280 (D.N.J. 2005). In an effort to minimize the formation of lactam during the manufacturing process, Warner Lambert developed a process disclosed and claimed in the '482 patent. Warner Lambert determined that two limitations must be observed in the process in order to achieve stable formations of gabapentin.

First, the '482 patent discloses that gabapentin must be highly purified before being formulated into the pharmaceutical preparation. While drug manufacturers generally prefer to use salt forms of an active ingredient over the free base form because salts "usually provide good stability and good solubility," '482 patent col.3 ll.61-65, Warner Lambert determined that gabapentin hydrochloride was less stable than free gabapentin. Id. col.3 ll.65-67. Thus, Warner Lambert sought to keep lactam formation to a minimum by preparing gabapentin in its highly purified form. The '482 patent discloses that:

> The active materials of formula (I) must be prepared as highly purified, nonderivatized free amino acids, for example, from the corresponding hydrochloride by ion exchange. The proportion of remaining hydrochloride admixtures should thereby not exceed 20 ppm. The same also applies to other mineral acids.

Id. col.5 ll.24-29. Thus, the patent teaches that in preparing purified gabapentin, the hydrochloride admixture, or other mineral acid, remaining from the manufacturing process should not exceed twenty parts per million ("20 ppm").

Second, Warner Lambert determined that certain adjuvants that reduce the stability of gabapentin must be avoided. The '482 patent further discloses that:

> The following adjuvant materials, for example, reduced the stability of the compounds (I) and should be avoided in the preparation of pharmaceutical compositions: modified maize starch, sodium croscarmelose, glycerol behenic acid ester, methacrylic acid co-polymers (types A and C), anion exchangers titanium dioxide, and silica gels such as Aerosil 200.

Id. col.5 ll.5-10.

Pursuant to the Hatch-Waxman Act, Warner Lambert filed suit against several generic drug companies that filed Abbreviated New Drug Applications ("ANDAs") with the Food and Drug Administration.[1] Those companies sought approval to market generic versions of Neurontin®. In their ANDAs, appellees committed to using Teva's gabapentin active pharmaceutical ingredient in their products. Gabapentin, 393 F. Supp. 2d at 283. Under the direction of the Judicial Panel on Multidistrict Litigation, the actions were consolidated for pretrial proceedings in the United States District Court for the District of New Jersey. Between 2001 and 2003, appellees filed various summary judgment motions, including motions for summary judgment of noninfringement and invalidity. During the pendency of those motions, Warner Lambert sought a preliminary injunction to enjoin IVAX, Purepac, and Teva from launching their products. Those motions were denied.

On August 25, 2005, the district court issued several rulings on the summary judgment motions. The court construed numerous claim terms. At issue in this appeal

[1] After filing suit against appellees, Warner Lambert filed similar lawsuits against other generic drug manufacturers. Appellees, who belong to the first group of defendants Warner Lambert sued, are "first wave" defendants. "Second" and "third" wave defendants, whose cases have also been consolidated for pretrial purposes with the underlying multidistrict litigation, are not part of the instant appeal.

are two of those terms, namely, "anion of a mineral acid" and "adjuvant." Those terms appear in representative claim 7, which has been asserted against appellees. It claims:

> 7. A stable and pure pharmaceutical composition in unit dry medicinal dosage form consisting essentially of:
>
> (i) an active ingredient which is gabapentin in the free amino acid, crystalline anhydrous form containing less than 0.5% by weight of its corresponding lactam and less than 20 ppm of an anion of a mineral acid and
>
> (ii) one or more pharmaceutically acceptable adjuvants that do not promote conversion of more than 0.2% by weight of the gabapentin to its corresponding lactam form when stored at 25ºC and an atmospheric humidity of 50% for one year.

'482 patent claim 7 (emphases added). Based on the intrinsic evidence, the court construed "anion of a mineral acid" as an "anion derived from a mineral acid." In re Gabapentin Patent Litig., 395 F. Supp. 2d 153, 163 (D.N.J. 2005). The court further construed "adjuvants" as a "subset of [eight particular] inactive ingredients that is intimately mixed with gabapentin to form the drug mixture, and thus [does not] refer to the ingredients of capsule shells or tablet coatings." In re Gabapentin Patent Litig., 395 F. Supp. 2d 140, 152 (D.N.J. 2005).

The district court granted appellees' motion for summary judgment of noninfringement based on Warner Lambert's failure to meet its burden of proof. The court determined that Warner Lambert failed to adduce sufficient evidence to establish that the accused products meet the limitation that the anions of a mineral acid do not exceed 20 ppm ("the 20 ppm limitation"). In opposing the motion for summary judgment, Warner Lambert submitted results from a comparative pH test performed by its analytical expert. Warner Lambert argued that those results created a genuine issue of material fact regarding whether the accused products met the 20 ppm limitation.

Based on the undisputed fact that the test had a ± 5 ppm margin of error, the court determined that that evidence was insufficiently precise to prove infringement, and thus granted summary judgment in favor of appellees.

On July 13, 2006, the court entered judgment of noninfringement based on the burden of proof motion in favor of appellees, pursuant to Federal Rule of Civil Procedure 54(b). Warner Lambert timely appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

We review the district court's grant of summary judgment de novo, reapplying the standard applicable at the district court. See Rodime PLC v. Seagate Tech., Inc., 174 F.3d 1294, 1301 (Fed. Cir. 1999). Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). In addition, in deciding a motion for summary judgment, "[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986).

A determination of infringement requires a two-step analysis. "First, the court determines the scope and meaning of the patent claims asserted. . . . [Second,] the properly construed claims are compared to the allegedly infringing device." Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc) (citations omitted). Step one, claim construction, is an issue of law, Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-71 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996), that we

review de novo, Cybor, 138 F.3d at 1456 (Fed. Cir. 1998). Step two, comparison of the claim to the accused device, requires a determination that every claim limitation or its equivalent be found in the accused device. See Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 29 (1997). Those determinations are questions of fact, and on summary judgment, the issue is whether there is no genuine issue of material fact regarding infringement. Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353 (Fed. Cir. 1998).

I.

On appeal, Warner Lambert argues that the district court erred by resolving factual disputes on summary judgment. According to Warner Lambert, the parties proffered conflicting expert opinions, based on different evidence and different methods of testing, regarding whether Teva's samples infringed the '482 patent. As such, Warner Lambert argues that genuine issues of material fact exist in the record, and thus summary judgment was not appropriate. Warner Lambert further argues that the district court applied the wrong legal standard. Warner Lambert argues that the court, instead of determining whether it was more likely than not that a particular sample could meet the 20 ppm claim limitation, improperly determined whether it was possible that that sample could exceed the 20 ppm limitation.

Appellees respond that the court properly granted summary judgment for several reasons. First, appellees challenge the accuracy and reliability of the pH testing method. Appellees assert that the pH testing method yielded inaccurate results because, inter alia, Warner Lambert's expert failed to calibrate the standards used for the test. Second, appellees argue that pH testing is not competent proof of infringement in light of the test's lack of precision. Because the pH testing method cannot quantify

the level of acidic chloride in a gabapentin sample, as Warner Lambert purportedly conceded, appellees argue that that evidence was insufficient to raise a genuine issue of material fact. As such, appellees contend that summary judgment was proper because appellees' evidence showing that the samples contained more than 20 ppm of acidic chloride stood unrebutted.

We agree with Warner Lambert that genuine issues of material fact exist in the record, and thus that the court erred in granting summary judgment. In support of its motion for summary judgment, appellees adduced evidence demonstrating that the Teva samples contained over 20 ppm of acidic chloride.[2] To counter that evidence, Warner Lambert submitted results from pH tests that were performed by Warner Lambert's analytical expert, Dr. Martin C. Davies. In conducting the comparative pH testing, Dr. Davies measured pH levels of the Teva samples against standards with known levels of acid. Dr. Davies prepared the standards by first preparing a baseline sample that contained no detectable chloride. Various known amounts of acid were then added to the baseline sample, and the pH measurements of the standard samples were recorded. The pH measurements of the standards generally decreased as the amount of mineral acid increased. Conversely, the pH measurements increased as the amount of mineral acid decreased. The pH values of numerous Teva samples were then measured. The record contains a chart prepared by Dr. Davies that compares those values to the pH measurements of the standard samples. The chart, reproduced

[2] Because hydrochloric acid ("HCl") is the mineral acid of interest in this action, the relevant inquiry is whether Teva's samples meet the requirement that they contain less than 20 ppm of anions derived from HCl. Anions derived from HCl are referred to as "acid-derived chloride ions" or "acidic chlorides." We will refer to the relevant anions as "acidic chloride" throughout the opinion.

below, includes pH measurements of seven Teva samples. The last five samples, 288074001-859173601, represent samples made according to a process that Teva implemented after the issuance of the '482 patent, and thus are relevant to our analysis. The results revealed, in pertinent part, the following:

pH MEASUREMENTS

HCl Added (ml)	Chloride Added (ppm from HCl)	Warner-Lambert Sample	Teva Samples						
		794311	288000997 (M1097)	288001898 (9950075)	288074001	859170401	859172101	859172301	859173601
0.0	0	7.06	7.09	7.07	7.02	6.97	6.99	7.02	7.02
0.25	6	7.01	7.06	7.04	7.01	6.93	6.95	6.98	6.97
0.50	12	6.98	7.03	7.01	6.99	6.90	6.94	6.96	6.94
0.75	18	6.96	7.01	6.98	6.94	6.88	6.90	6.90	6.91

For purposes of this appeal, the standard sample containing 12 ppm of chloride, which had a pH value of 6.98, is dispositive of the issue before us. Standing alone, that standard indicates that a sample with a pH of 6.98 would have 12 ppm of acidic chloride, which would meet the 20 ppm limitation. Taking into account the test's margin of error of ± 5 ppm, the 12 ppm standard further indicates that a sample with a pH of 6.98 could have between 7 to 17 ppm of acidic chloride—a range that falls within the 20 ppm claim limitation. Significantly, four out of the five relevant Teva samples had pH values that were greater than 6.98,[3] which, according to Dr. Bartlett, indicates that those four samples contained not more than 17 ppm of acidic chloride, thereby also meeting

[3] The pertinent data with regard to the Teva samples are found in the first row, which represents pH values for pure gabapentin samples, i.e., samples to which no HCl was added.

the 20 ppm claim limitation.[4] See J.A. 1459-60. Drawing all reasonable inferences in favor of Warner Lambert as the nonmovant, we conclude that Warner Lambert adduced sufficient evidence to create a genuine issue of material fact regarding whether Teva's samples met the 20 ppm claim limitation of the '482 patent. Accordingly, the district court erred in granting summary judgment.

We are unpersuaded by appellees' complaint concerning the validity of the comparative pH testing method. In moving for summary judgment of noninfringement based on Warner Lambert's inability to meet its burden of proof, appellees informed the district court that:

> It is important to note for the record that Defendants strongly dispute the capability of pH testing to make any scientifically meaningful distinctions between gabapentin samples at the trace levels of acidity relevant to the '482 patent. However, for purposes of this motion, Defendants have placed that dispute to one side (as they must), and focused on the undisputed limitations on the precision of such comparative pH measurements.

Indeed, at the summary judgment hearing, appellees expressly stated that:

> Teva's experts vehemently dispute the validity of the data [Dr. Bartlett] relied on, but I want to ignore that dispute. Those factual issues are in dispute, but should not be part of this motion, and we, you can ignore them.

Thus, appellees limited their summary judgment motion to the issue of the undisputed limits of the test's precision, viz., the ± 5 ppm margin of error, which we have considered. As such, appellees waived any argument challenging the validity, including

[4] A higher pH value represents lower acidity. Gabapentin, 393 F. Supp. 2d at 284. Thus, "[i]f the pH of the unknown sample measures higher than a particular standard, then that sample must contain less acid," and hence a lesser amount of acidic chlorides, than the standard. Id. at 285.

challenges to the accuracy or reliability, of the pH testing method for purposes of summary judgment.

Moreover, we are not persuaded by appellees' argument that summary judgment was proper because Warner Lambert failed to prove infringement in quantitative terms. Appellees rely on Abbott Laboratories v. TorPharm, Inc., 300 F.3d 1367 (Fed. Cir. 2002), and Zenith Laboratories, Inc. v. Bristol-Myers Squibb Co., 19 F.3d 1418 (Fed. Cir. 1994), in support of their argument that infringement must be proven using a test that can quantify the level of acidic chloride in a gabapentin sample because Warner Lambert chose to draft its claims in quantitative terms. Appellees' reliance on the cited authority is misplaced. In Abbott, the patentee defined the scope of his claims in terms of "oligomeric structure and the number of repeating units." 300 F.3d at 1376. We concluded that the patentee was required to demonstrate infringement in terms of those properties, rather than rely on molecular weight measurements that purportedly failed "to provide proof of molecular structure." Id. at 1377. Similarly, in Zenith, the patentee drafted his claims in terms of x-ray diffraction properties. We stated that "the scientific theories utilized must establish the presence of the limitations recited in the claim," and thus found that two types of tests proffered by the patentee, namely, visual observation and birefringence comparison, were only "inferentially relevant" in proving infringement because they failed to establish whether crystals possessed the claimed x-ray diffraction properties. 19 F.3d at 1423.

Here, in order to prove infringement, Warner Lambert is required to demonstrate that the Teva samples contain less than 20 ppm of anions of a mineral acid, as recited in the claims. Based on the record before us, the comparative pH testing allows for this

showing. Unlike the evidence relied on in Abbott and Zenith, pH testing can indicate whether a sample contains less than 20 ppm of acidic chloride by measuring the pH, or acidity, of the solution and comparing it against a sample with a known amount of acid. Dr. Bartlett opined that "[i]f the pH of the unknown sample measures higher than a particular standard, then that sample must contain less acid than the standard. Using the comparative pH technique, one can thus determine whether the unknown sample falls within the acid limitation of the '482 patent." To the extent appellees are arguing that the comparative pH testing method is invalid, inaccurate, or unreliable, as discussed above, appellees waived that argument for purposes of summary judgment.

Accordingly, based on the record before us, we conclude that the district court erred in granting summary judgment of noninfringement based on Warner Lambert's purported failure to meet its burden of proof. The record shows that Warner Lambert proffered sufficient evidence to create a genuine issue of material fact regarding whether the accused products met the 20 ppm claim limitation of the '482 patent.

II.

Appellees argue in the alternative that the judgment can be affirmed because the court erred in its construction of the "anion of a mineral acid" and adjuvant claim limitations, and that they should still be awarded judgment, but based on what they consider to be the correct claim interpretation. Appellees assert that based on the intrinsic evidence, and the prosecution history in particular, "anion of a mineral acid" refers to anions from any source capable of forming a mineral acid. In essence, appellees assert that the term refers to total chloride content and is not limited to acid-derived chloride ions. Under that interpretation, they argue they do not infringe.

Appellees further argue that the court correctly concluded that the adjuvant limitation excludes the eight adjuvants identified in the specification of the '482 patent, but erred in concluding that the adjuvant must be intimately mixed with the gabapentin. According to appellees, adjuvant refers to any ingredient other than the active ingredient, and thus encompasses ingredients included in the capsule shell or tablet coating. Because certain accused products include titanium dioxide, one of the excluded adjuvants, in the capsule shell or tablet coating, appellees contend that those products do not infringe. Appellees also challenge the court's construction of the term "modified maize starch," which is identified as one of the adjuvants to be avoided. Under the proper construction of that term, which appellees argue would include pregelatinized starch, appellees contend that their samples likewise would not infringe.

Warner Lambert responds that the court's construction of those terms was correct. As for "anion of a mineral acid," Warner Lambert contends that appellees' proffered construction would read the term "of a mineral acid" out of the claims. Additionally, Warner Lambert asserts that the court's construction is correct in light of the intrinsic evidence and the purpose of the invention. With respect to the adjuvant limitation, Warner Lambert argues that appellees are precluded from appealing that issue because it was not the subject of the Rule 54(b) motion. In the alternative, Warner Lambert asserts that appellees' proposed constructions are contrary to both the intrinsic and extrinsic evidence.

We first address the claim limitation of "anion of a mineral acid," which is present in every asserted claim of the '482 patent. We agree with the district court that the proper construction is "anion derived from a mineral acid." In re Gabapentin Patent

Litig., 395 F. Supp. 2d 153, 159 (D.N.J. 2005). "It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" Phillips v. AWH Corp., 415 F.3d 1303, 1327 (Fed. Cir. 2005) (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004)). Here, the plain language of the claim supports the construction that the anion specifically is derived from a mineral acid. Appellees' assertion that the claimed anion refers to total chloride ions or anions from any source that is "capable of" forming a mineral acid is unsupported by the claim language. Had the patentees intended the anion to refer to any anion, regardless of its source, the patentees could have simply claimed "anions" and omitted the phrase "of a mineral acid." Thus, the construction adopted by the district court gives full meaning to every word of the entire claim term. Bicon, Inc. v. Straumann Co., 441 F.3d 945, 950 (Fed. Cir. 2006) ("claims are interpreted with an eye toward giving effect to all terms in the claim"). Moreover, reference to other claims of the patent further supports this definition. Dependent claims 2, 5, 6, and 11 specify that the mineral acid is hydrochloric acid. Those dependent claims would be superfluous or unnecessary if the anions did not derive from mineral acids because there would be no need to identify with particularity the type of mineral acid that must be used. Therefore, based on the claim language, we conclude that the district court did not err in its construction.

We have also held that claims "must be read in view of the specification, of which they are a part." Phillips, 415 F.3d at 1315. While appellees argue that the specification provides no support for their construction, we find that the specification provides further support for the construction adopted by the district court. The specification teaches a

multi-step process for making gabapentin that is substantially free from lactam. '482 patent Abstract, col.1 l.41-col.2 l.21. The Summary of the Invention describes a three-step process as:

> (a) treating a compound of formula VII substantially free from compound VIII with a semiconcentrated mineral acid, converting the lactam VIII into VII,
>
> (b) removing the anions of the mineral acid by ion exchange, leaving the purified VII, and
>
> (c) converting the product of step (b) to a pharmaceutically acceptable salt thereof, if desired.

Id. col.2 ll.1-8 (emphases added). The specification then states that "[a] preferred process of the instant invention is one wherein the mineral acid hydrochloric acid is used and an ion exchanger is used for anion removal." Id. col.2 ll.9-10. That disclosure further supports the conclusion that the anions that are to be removed are specific to the mineral acid that was used in the first step of the process, and do not derive from any other possible source.

We are not persuaded by appellees' extensive reliance on the prosecution history in support of their construction, particularly in this case where the claim language provides a clear definition of the disputed claim term, supported by the specification. Based on our review of the prosecution history, we find no basis for reversing the district court's construction, which we have already determined comports with the claim language and specification. Accordingly, we conclude that the district court did not err in its construction of the claim term "anion of a mineral acid."

We next consider appellees' arguments concerning adjuvants. As a preliminary matter, we disagree with Warner Lambert's assertion that the adjuvant issue is not

properly before us because it falls outside the scope of the Rule 54(b) judgment. Rule 54(b) provides that:

> When more than one claim for relief is presented in an action, whether as a claim, counterclaim, cross-claim, or third-party claim, or when multiple parties are involved, the court may direct the entry of a final judgment as to one or more but fewer than all of the claims or parties only upon an express determination that there is no just reason for delay and upon an express direction for the entry of judgment.

Here, finding no just reason for delay, the district court entered final judgment on Warner Lambert's infringement claims. In reaching its decision to grant the request for certification under Rule 54(b), the district court reasoned that "Federal Circuit review of the Court's claim constructions and noninfringement rulings will advance the ultimate resolution of this multidistrict litigation." R. 54(b) Order, slip op. at 3. The court further stated that "appellate review will benefit the parties in this multidistrict litigation by providing definitive claim constructions, which should narrow the issues." Id. at 4. Thus, contrary to Warner Lambert's assertion, the court's entry of final judgment on the issue of noninfringement was not limited to two particular motions, viz., the burden of proof motion or Apotex's adjuvant motion, but rather encompassed the court's claim construction rulings that pertained to the issue of noninfringement. As such, the court's claim construction of the adjuvant limitation, which is relevant to a noninfringement determination, is properly before us.

We agree with Warner Lambert that the district court did not err in concluding that the adjuvant claim limitation refers to ingredients intimately mixed with gabapentin, and thus excludes ingredients located in the capsule shell or tablet coating. In reaching its determination, the court first examined the claim language. The court noted that claim 7 claimed "a stable and pure pharmaceutical composition in unit dry medicinal

dosage form," thus suggesting a distinction between ingredients that are mixed with the active ingredients and ingredients that are separated from the active ingredient because they are in the tablet coating or capsule shell. Gabapentin, 395 F. Supp. 2d at 151-52. The court then considered the specification and correctly observed that the patentees were concerned with the negative effect certain adjuvants had on the stability of gabapentin because those adjuvants catalyzed lactam formation. The court concluded that "that concern is most relevant where the catalyst is intimately mixed with the reactive material, suggesting to the Court that peripheral or partial contact, as in a capsule shell or tablet film coating, between a catalyst and the reactive material was of lesser concern." Id. at 152. Moreover, the court found nothing in the patent or prosecution history indicating that ingredients found in the capsule shell or coating affects stability, and also relied on several dictionary definitions in support of its construction. We find no error in the court's analysis, and are not persuaded by appellees' arguments in support of a broader definition. Accordingly, we conclude that the court did not err in determining that the asserted claims require the adjuvant to be intimately mixed with gabapentin.

Lastly, we reject appellees' assertion that the court erred in construing "modified maize starch" as "maize starch modified by acid treatment." In reaching its conclusion, the court first examined the '482 patent specification. The specification discloses that:

> The following adjuvant materials, for example, reduced the stability of the compounds (I) and should be avoided in the preparation of pharmaceutical compositions: modified maize starch, sodium croscarmelose, glycerol behenic acid ester, methacrylic acid co-polymers (types A and C), anion exchangers titanium dioxide, and silica gels such as Aerosil 200.
>
> On the other hand, the following adjuvant materials had no noticeable influence on the stability of the compounds (I):

> hydroxypropylmethylcellulose, polyvinylpyrrolidone, crospovidon, poloxamer 407, poloxamer 188, sodium starch glycolate, copolyvidone, maize starch, cyclodextrin, lactose, talc, as well as co-polymers of dimethylamino-methacrylic acid and neutral methacrylic acid ester.

'482 patent col.5 ll.5-17 (emphases added). The court noted that while the specification expressly indicated that modified maize starch should be avoided as an adjuvant, the specification further stated that sodium starch glycolate, which, according to Warner Lambert's expert, Dr. Klibanov, is an example of pregelatinized starch, "had no noticeable influence on the stability of the compounds." That supports the court's construction that modified maize starch does not encompass pregelatinized starch; otherwise the teaching of the specification would be internally inconsistent.

In addition, the court relied on the prosecution history in support of its construction. The prosecution history contains a declaration dated December 10, 1999, by Dr. Friedrich Tröndlin, then-head of the analytical department of Parke-Davis Analytical Research. Dr. Tröndlin stated that "it is my belief that excipients pretreated with mineral acids, such as maize starch modified by acid treatment would not result in a stable formulation." That statement provides further support for the construction adopted by the district court. Based on those references to the intrinsic evidence, we thus conclude that modified maize starch refers to maize starch modified by acid treatment, which therefore excludes pregelatinized starch.

We have considered appellees' arguments regarding the court's claim construction and find none that warrant reversal of the district court's decision. In light of our conclusion, we thus reject appellees' alternative argument for noninfringement.

CONCLUSION

For the foregoing reasons, we reverse the district court's grant of summary judgment of noninfringement, affirm the court's claim construction of the "anion of a mineral acid" and adjuvant claim limitations, and remand for further proceedings consistent with this opinion.

REVERSED IN PART, AFFIRMED IN PART, AND REMANDED